IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CATILINA NOMINEES PROPRIETARY LTD., et al.,	)	
Plaintiffs and Counter-Defendants,	)	No. 15-cv-10734
v.	)	Judge Andrea R. Wood
STERICYCLE, INC.,	)	
Defendant and Counter-Plaintiff.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs and Counter-Defendants Catilina Nominees Proprietary Ltd. ("Catilina") and Daniels Sharpsmart, Inc. ("Sharpsmart") are the owner and exclusive licensee, respectively, of a patent for a container for the disposal of medical sharps and waste materials. Together, they have sued Defendant and Counter-Plaintiff Stericycle, Inc. ("Stericycle"), alleging infringement of U.S. Patent No. 6,250,465 ("'465 patent") and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a), with respect to Stericycle's own sharps container. Stericycle, in turn, has asserted counterclaims against Plaintiffs, seeking a declaratory judgment that the '465 patent is invalid and not infringed by Stericycle and that Stericycle has not committed acts of false advertising or unfair competition. Before the Court is Stericycle's renewed motion for summary judgment of noninfringement. (Dkt. No. 201.) For the following reasons, the motion is granted in part and denied in part.

BACKGROUND

Unless otherwise noted, the following facts are undisputed.

I. The ’465 Patent

Catilina owns the ’465 patent, titled “Sharps Container,” for a container for disposing of medical sharps and waste materials that prevents hand access into the container. (Def.’s Mem., Ex. 12, ’465 patent at 1, Dkt. No. 201-12.) Sharpsmart offers the Sharpsmart Container as one of its products. (Def.’s Resp. to Pls.’ Statement of Additional Facts (“DRPSF”) ¶ 1, Dkt. No. 225-1.) Plaintiffs contend that Sharpsmart has continuously marked the Sharpsmart Container with the ’465 patent—an assertion Stericycle contests. (*Id.*) The ’465 patent expired on May 14, 2019. (Pls.’ Resp. to Def.’s Statement of Facts (“PRDSF”) ¶ 10, Dkt. No. 216-1.)

Plaintiffs allege that Stericycle infringed claims 22–24 of the ’465 patent. (*Id.* ¶¶ 4, 6.) Claim 22, with reference to claim 21, recites that the “‘pivotal tray’ of the sharps and waste ‘container’ is ‘arranged relative to the lid in its opened position and arranged relative to the receptacle and its opening to prevent hand access into the receptacle for all positions of the tray about its pivotal axis.’” (*Id.* ¶ 7.) Claim 23 and claim 24, with reference to claim 23, describe a container where, “‘in the opened position of the lid the disposing tray impedes hand access into the receptacle’ and ‘whereby said front portion of the tray moves toward said lid to continue to impede hand access into the receptacle.’” (*Id.* ¶ 8.) In a prior ruling, the Court construed the claim terms “prevent hand access into the receptable” and “impede hand access into the receptacle” as meaning:

> [M]ake it so that a person who is using the container, as well as others who may come into contact with the container, cannot extend their hand(s), or portion of their hand(s), into the receptacle that holds medical sharps and waste, thereby substantially eliminating injury or infectious transmission by preventing human contact with medical sharps and waste.

(12/18/2018 Mem. Op. and Order at 30, Dkt. No. 62.)

II. Stericycle's Horizontal Lid Sharps Containers

Stericycle offers the Stericycle Sharps Management Service Reusable Sharps Container as a product. (PRDSF ¶ 43.) In a regulatory filing with the Food and Drug Administration ("FDA"), Stericycle describes its sharps container as using "a counterbalanced lid design that acts as a protective barrier to keep sharps objects within the container from coming back up through the lid and anyone from reaching into the container to retrieve sharps waste." (DRPSF ¶ 15.) Likewise, in promotional materials, Stericycle characterizes its product as "utiliz[ing] safety/engineering controls that prevent[] access to the contents of the container," "incorporat[ing] safety/engineering controls that include limited access to the contents of the container," and causing a "100% sustained reduction in needlesticks." (*Id.* ¶ 16.)

Commercial Plastics (and its predecessor Xten Industries) manufactured and shipped Stericycle's PGII Horizontal Lid Sharps Container ("PGII container"). (PRDSF ¶ 19.) The design of the PGII container consists of two moving parts: the inner door and the outer door. (*Id.* ¶ 18.) Each PGII container also has a black line labeled "FILL LINE" to indicate to users when to stop adding waste to the container. (*Id.* ¶ 19.)

Prior to July 7, 2014, Commercial Plastics manufactured and shipped 1,706 PGII containers into the United States, 2,261 into Canada, and 1,900 into the United Kingdom. (*Id.* ¶ 23.) Stericycle refers to these groups of PGII containers made before July 7, 2014, as the "testing and sample designs" because it views them as preliminary designs intended for testing or for use as samples. (*Id.* ¶ 22.) Plaintiffs, however, assert that these were still commercial uses. (*Id.* ¶ 22.) With respect to structure, the testing and sampling designs had a longer inner door than later designs, resulting in a smaller opening between the interior section of the inner and outer doors. (*Id.* ¶¶ 38–39.) Ultimately, Stericycle received approximately £40,716.93 in revenue associated with those designs in the United Kingdom. (*Id.* ¶ 25.) But it received no revenue associated with those designs in the United States and Canada. (*Id.* ¶ 24.)[1]

Around July 7, 2014, Stericycle altered the design of the PGII container by shortening the length of the inner door's interior by a half-inch. (*Id.* ¶ 26.) Stericycle commercialized this design, and Commercial Plastics manufactured and shipped 18,178 of the products into the United States, 6,428 into Canada, and 12,628 into the United Kingdom. (*Id.* ¶¶ 28–29.) Stericycle refers to those groups of the PGII containers made after July 7, 2014, as the "commercialized designs." (*Id.* ¶ 30.)

III. Stericycle's Alleged Infringement

The parties dispute which versions of Stericycle's horizontal drop lid sharps containers Plaintiffs identified as the accused instrumentalities in their infringement contentions. Stericycle asserts that Plaintiffs identified only two versions of Stericycle's allegedly infringing products in

[1] Stericycle's statement that it received no revenue from its testing and sampling designs in Canada and the United States is deemed admitted, despite Plaintiffs having disputed the claim. To contest the claim properly, Plaintiffs were required to point to specific evidence in the record. *See* L.R. 56.1(b)(3)(A). They did not do so.

their amended contentions: the PGII Horizontal Lid Sharps Container (first version) and the "horizontal drop lid sharps container distributed in, at a minimum, the United Kingdom" (second version). (*Id.* ¶¶ 11–14.) For their part, Plaintiffs contend that they also identified PGII containers with two different lid versions—PGII Lid Version 1 and PGII Lid Version 2—in their Second Amended Complaint ("SAC"). (*Id.* ¶¶ 11–12.) Additionally, Stericycle contends that both the first and second versions of the horizontal lid sharps containers are the commercialized version of the PGII container made after July 7, 2014, with the only difference between the two being the color of the plastic used on the container and lid. (*Id.* ¶ 15.) In contrast, Plaintiffs claim that the first version, which has a red container and black lid, has a longer lid and is manufactured using different engineering specifications. (*Id.* ¶ 15.)

For both the commercialized design and the testing and sample design of the PGII container, the parties also disagree on the degree of hand access into the container's receptacle. For the commercialized design, Stericycle contends that the design allows a person to extend part of their fingers to or beyond the fill line; on the other hand, Plaintiffs assert that at least in some instances, the design did not permit a person to extend their fingers to or beyond the fill line. (*Id.* ¶ 30.) With respect to the testing and sample design—which had a longer inner door—Stericycle claims that a person could still extend part of their hand into the receptacle, while Plaintiffs argue that at least in some instances, the design prohibited a person from extending their hand into the receptacle. (*Id.* ¶¶ 39, 41–42.)

DISCUSSION

The Court grants summary judgment when the admissible evidence considered as a whole shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law, even after all reasonable inferences are drawn in the non-movant's

favor. *Dynegy Mktg. & Trade v. Multiut Corp.*, 648 F.3d 506, 517 (7th Cir. 2011). A genuine dispute exists where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Zaya v. Sood*, 836 F.3d 800, 804 (7th Cir. 2016) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

Here, Stericycle argues that it is entitled to summary judgment of noninfringement for both the commercialized design and the testing and sample design of Stericycle's PGII container—either under a literal infringement theory or a doctrine of equivalents theory—since its designs do not prevent hand access into the container's receptacle. Further, Stericycle contends that it is entitled to summary judgment in its favor with respect to its liability for alleged infringement with respect to manufactured designs of the PGII container shipped to foreign countries because it engaged in no infringing activity within the United States for those products. Finally, Stericycle argues that Plaintiffs are not entitled to recover damages for any infringement prior to the filing date of this lawsuit due to Plaintiffs' failure to mark the Sharpsmart container with the '465 patent or provide notice of Stericycle's allegedly infringing activity before suit.

I. Dispute Over the Design Versions of the PGII Container

As an initial matter, Plaintiffs argue that summary judgment is inappropriate because there is a genuine dispute of fact concerning the differences between design versions of the accused product. Specifically, Plaintiffs claim that Stericycle failed to disclose the existence of alternative designs throughout discovery, and that they only discovered the existence of the testing and sample designs from a third party. As a result, according to Plaintiffs, Stericycle's "bad faith" has created issues of fact and confusion regarding the physical characteristics and sales figures for each design version.

The Court is unpersuaded that the record demonstrates a genuine dispute of fact concerning design versions of the PGII container. At a status hearing approximately one month before Stericycle filed its summary judgment motion, Plaintiffs advised the Court that they had recently discovered that there were multiple versions of the lid for the PGII container. (3/8/2022 Status Hr'g Tr. 6:1–10, Dkt. No. 219.) Yet Plaintiffs also responded "no" to the Court's question about whether they required additional discovery related to their patent claim. (*Id.* 6:24–7:12.) And Plaintiffs referred only to the existence of two versions of the container ("version one" and "version two") at the same hearing. (*See id.* 6:1–23.) In Plaintiffs' interrogatory responses for their false advertising claim, which Plaintiffs submitted less than a month before filing their response brief, Plaintiffs also continued to refer to two versions of the PGII container: a pre-July 2014 version ("Version 1") and a July 2014 version ("Version 2"). (Def.'s Reply Br., Ex. 2, Pls.' Resp. to Third Set of Interrogs. at 9, Dkt. No. 225-2.)

Moreover, Plaintiffs elected not to file a motion under Federal Rule of Civil Procedure 56(d) for the Court to defer considering Stericycle's summary judgment motion or deny it, so that Plaintiffs could obtain additional discovery on design differences. Plaintiffs clearly knew how to utilize Rule 56(d) as the Court previously granted, in part, Plaintiffs' prior Rule 56(d) motion in July 2019. (7/9/2019 Minute Entry, Dkt. No. 95.) Additionally, in February 2020, the Court extended the fact discovery deadline and authorized Plaintiffs to compel supplemental discovery from Stericycle regarding the earlier designs of the PGII container. (2/26/2020 Minute Entry, Dkt. No. 130.) Taken together, these facts undermine Plaintiffs' contention that there is a dispute over the design versions at issue.

Further, Plaintiffs do not cite evidence in the record to support their accusations of bad faith, nor do they reference any authority for the proposition that an opposing party's bad faith

creates disputed issues of material fact. Federal Rule of Civil Procedure 56 requires a party asserting that a fact is genuinely disputed to support its assertion with evidence in the record. Fed. R. Civ. P. 56. Plaintiffs have not done so. Consequently, the Court will not deny Stericycle's summary judgment motion on this ground.

II. Alleged Violation of Local Patent Rules

Before addressing the merits of Plaintiffs' patent infringement claim, the Court considers whether Plaintiffs identified the testing and sample designs of the PGII container in their amended final infringement contentions. Stericycle objects to the inclusion of the testing and sample designs as part of Plaintiffs' claim, asserting that Plaintiffs failed to include an analysis of the designs in their claim chart as directed by the local patent rules. Despite Stericycle's objection, it still seeks summary judgment of noninfringement for the testing and sample designs.

Local Patent Rule 3.1 requires a patentee to serve final infringement contentions containing certain information, including an identification of each of the opposing party's accused devices of which the patentee is claiming infringement and a chart identifying where each element of an asserted claim is found within the accused device. LPR 3.1, 2.2. A party may amend its final infringement contentions "only by order of the Court upon a showing of good cause and absence of unfair prejudice to opposing parties, made promptly upon discovery of the basis for the amendment." LPR 3.4.

Local patent rules are "essentially a series of case management orders," and district courts may "impose any 'just' sanction for the failure to obey a scheduling order." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006); *see also Medline Indus., Inc. v. C.R. Bard, Inc.*, 511 F. Supp. 3d 883, 888 (N.D. Ill. 2021) (noting that courts have "broad discretion to manage discovery matters and enforce the Local Patent Rules"). For instance, courts

may exclude evidence as a sanction for a party's failure to comply with local patent rules. *Phigenix, Inc. v. Genentech, Inc.*, 783 F. App'x 1014, 1020 (Fed. Cir. 2019) (citing *O2 Micro*, 467 F.3d at 1369). Local patent rules are designed to "prevent a 'shifting sands' approach to claim construction by forcing the parties to 'crystallize their theories of the case early in litigation.'" *Fujitsu Ltd. v. Tellabs Operations, Inc.*, No. 08 C 3379, 2012 WL 5444979, at *4 (N.D. Ill. Mar. 21, 2012) (quoting *O2 Micro*, 467 F.3d at 1364).

Here, it is undisputed that Plaintiffs' amended final infringement contentions identify two versions of the PGII container as allegedly infringing devices: (1) PGII Horizontal Lid Sharps Container and (2) horizontal lid sharps container that is distributed, at a minimum, in the United Kingdom. (PRDSF ¶¶ 13–14.) In their claim chart, Plaintiffs further note that the first version has "a lower red portion and upper black portion," and the second version "has a lower yellow portion and an upper red portion (which also may be yellow, blue, or purple)." (Def.'s Mem., Ex. 11, Pls.' Am. Final Infringement Contentions at 10, Dkt. No. 201-11.) Stericycle argues that both versions of the accused devices identified in the amended contentions are the commercialized version of the PGII container. In support, Stericycle offers an affidavit from Brian Foos, Stericycle's director of container strategy and control, stating that the photographs of the different versions in the amended contentions are of the commercialized designs. (Def.'s Mem., Ex. 2, Foos Decl. ¶¶ 2, 4–5, Dkt. No. 202-2.) Plaintiffs, in turn, assert that that they believe the first version to be the testing and sample design. However, Plaintiffs rely solely on the SAC, in which they identify version one of the PGII container as the version with a wider inner door and manufactured from 2011 to 2014, which would be the testing and sample design. (*See* SAC ¶¶ 25–26, 30.) And Plaintiffs provide no evidence to contradict Stericycle's evidence that the first version identified in their final infringement contentions and claim chart is the commercialized design. In their final amended

contentions, Plaintiffs also do not describe the first version as having a longer lid or inner door than the second version. (*See* Pls.' Am. Final Infringement Contentions at 3, 10.)

Therefore, the Court concurs with Stericycle that the final infringement contentions did not properly identify the testing and sample designs as an accused device. Indeed, Plaintiffs also failed to seek leave to amend their final infringement contentions to include the testing and sample designs as part of their infringement claim upon their discovery of those designs, as permitted by Local Patent Rule 3.4. As a result, the Court finds that Plaintiffs violated Local Patent Rule 3.1's requirements for final infringement contentions.

Nonetheless, the Court—in an exercise of its discretion—excuses Plaintiffs' non-compliance with an admonishment that it not be repeated. Stericycle does not argue that it has been prejudiced by Plaintiffs' failure nor does there appear to be any prejudice. The parties obviously conducted some discovery on the testing and sample designs because Plaintiffs submitted an affidavit of a person who attempted to reach his hand into the PGII container marked exhibit P57, which Stericycle contends is one of the testing and sample designs. (DRPSF ¶ 11.) Additionally, Stericycle conducted several depositions where its counsel questioned deponents on the features and capabilities of the testing and sample designs. (*See*, *e.g.*, Def.'s Mem., Ex. 4, Foos Dep., Dkt. No. 202-4; Def.'s Mem., Ex. 5, Dirr Dep., Dkt. No. 202-5; Def.'s Mem., Ex. 10, Biba Dep., Dkt. No. 202-10.) Further, Plaintiffs previously identified a pre-July 2014 version of the PGII container as an allegedly infringing device in their complaint. (*See* SAC ¶¶ 25–30.) Thus, Stericycle knew of Plaintiffs' prior allegations regarding this version prior to the summary judgment stage.

Accordingly, the Court will consider the testing and sample designs of the PGII container as part of Plaintiffs' patent infringement claim.

III. Patent Infringement

Next, the Court considers the merits of Plaintiffs' patent infringement claim. Stericycle contends that its designs did not infringe claims 22-24 of the '465 patent, either under a literal infringement theory or a doctrine of equivalents theory.

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). To assess whether an accused device infringes, courts must engage in a two-step analysis: (1) "determine[] the scope and meaning of the patent claims asserted"; and (2) compare the properly construed claims to the allegedly infringing device. *Sound View Innovations, LLC v. Hulu, LLC*, 33 F.4th 1326, 1335 (Fed. Cir. 2022) (internal quotation marks and citation omitted). Summary judgment is appropriate for an infringement claim, whether literal or under the doctrine of equivalents, "when no reasonable factfinder could find that the accused product contains every claim limitation or its equivalent." *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1339 (Fed. Cir. 2016) (citations omitted).

A. Claim Construction of "Prevent Hand Access"

In a prior ruling, the Court performed step one of the analysis when it construed disputed terms in the patent-in-suit. (*See* 12/18/18 Mem. Op. and Order.) Relevant here, the Court construed the terms "prevent hand access into the receptacle" and "impede access into the receptacle" in claims 22-24 to mean:

> [M]ake it so that a person who is using the container, as well as others who may come into contact with the container, cannot extend their hand(s), or portion of their hand(s), into the receptacle that holds medical sharps and waste, thereby substantially eliminating injury or infectious transmission by preventing human contact with medical sharps and waste.

(*Id.* at 30.)

Presently, the parties debate what the Court's construction of "prevent hand access into the receptacle" actually means in relation to Stericycle's PGII container. Much of the controversy stems from the following footnote in the claim construction order:

> The Court notes that, as recited above, the [patent] specification indicates that hand access is prevented with respect to the "storage section of the receptacle" and then goes on to suggest that the storage section may not be the entire volume of the receptacle. However, claims 21–24 only recite that hand access is prevented or impeded "into the receptacle," not "into the storage portion of the receptacle." (*Id.* at 15 16:14, 41–43, 47.) The Court sees no need to identify in its construction whether the hand access must be prevented specifically with respect to the storage portion of the receptacle. The Court's construction makes clear that the prevention of access substantially eliminates injury or infectious transmission by preventing human contact with medical sharps and waste; such contact can only occur when the hand (or its portion) reaches the medical waste that is stored in the receptacle, in what the patent-in-suit calls the "storage section of the receptacle."

(*Id.* at 14 n.3.) Plaintiffs argue that the "prevent hand access into the receptacle" limitation refers not to the entire volume of the receptacle, but instead to the portion of the receptacle that actually stores the medical sharps and waste; in this instance, the area below the fill line in the PGII container. On the other hand, Stericycle contends that the Court's construction signifies that hand access into any part of the receptacle is prohibited; hence, it was unnecessary for the Court to use the language "storage section of the receptacle," which is a smaller area of the receptacle than the entire region.

Neither party is quite correct. The footnote clarifies that the Court did not need to add the language "storage section of the receptacle" from the specification to its construction because it is plain that human contact with medical sharps and waste can only occur if a hand or a portion of a hand reaches the medical waste stored in the receptacle, and medical waste would only be found in what the patent-in-suit calls "the storage section of the receptacle." So, Stericycle's position

that preventing hand access into the receptacle refers to all areas of the receptacle does not comport with the Court's construction.

While the Court concurs with Plaintiffs that "prevent hand access into the receptacle" refers to the section where medical waste and sharps are stored, it does not agree that the area near or below the fill line is necessarily that area. It is undisputed that the fill line on the PGII container indicates to users when to stop adding waste to the container. (PRDSF ¶ 19.) Yet a user could presumably decide to ignore this recommendation and continue to add waste above the fill line, since there is no mechanism to prevent the user from doing so. In other words, waste could be stored throughout the entire receptacle. Plaintiffs rely on language in the specification stating that the receptacle preferably includes a window to observe the level of waste in the container, and the window "may include a mark for indicating that the receptacle is full." ('465 patent at 13:32–35.) But claims 22-24 do not recite a mark for indicating that the receptacle is full, or a "fill line." Rather, the fill line is a feature of Stericycle's PGII container. And it would be imprudent for the Court to construe the storage section of the receptable as the area below the fill line because infringement would vary according to an alleged infringer's placement of a mark on its container. Further, the specification is unclear on what the storage section exactly is, except that the "storage section of the receptacle preferably comprises a substantial portion of the receptacle volume and preferably includes the entire volume of the receptacle save for a section adjacent the opening." (*Id.* at 5:65–6:1.)

Thus, the Court clarifies that the phrase "receptacle that holds medical sharps and waste, thereby substantially eliminating injury or infectious transmission by preventing human contact with medical sharps and waste" in the Court's construction of "prevent hand access into the receptacle" refers to the area of the receptacle in which medical waste and sharps are stored where

a person's hand, or a portion of their hand can reach such medical waste and sharps stored there. This area may include the region of the receptacle above a fill line or similar mark, or the entire volume of the receptacle, so long as it does not include a section adjacent the opening.

B. "Reasonably Capable" of Infringement

As a threshold matter, Plaintiffs contend that Stericycle must show that the PGII container is not reasonably capable of infringement to be entitled to summary judgment, specifically that the lid arrangement is not reasonably capable of preventing hand access into the receptacle. Conversely, Stericycle argues that the reasonably capable standard is inapplicable because the claim language of the '465 patent does not recite capability, such as the container's tray being capable of preventing hand access into the receptacle.

"[W]here claim language recites capability, as opposed to actual operation, an apparatus that is reasonably capable of performing the claimed functions without significant alterations can infringe those claims." *ParkerVision, Inc. v. Qualcomm Inc.*, 903 F.3d 1354, 1362 (Fed. Cir. 2018) (internal quotation marks and citation omitted) (determining that the claim recited capability where the claim recited an oscillating signal that "causes said switch module ***to gate*** said bias signal and thereby generate a periodic signal having a plurality of harmonics," meaning that the apparatus required only an oscillating signal reasonably capable of gating the bias signal); *cf. Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1217 (Fed. Cir. 2014) (finding that the claim used language reciting capability where the claim recited "a processor ***for arranging*** information for transmission"); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204–05 (Fed. Cir. 2010) (noting that the claims described capabilities where the claims recited software components with specific purposes, such as "a logical engine ***for preventing*** execution").

A claim element does not recite capability where an apparatus requires a certain configuration, structure, or function, instead of a capacity to perform a function. *Cf. Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 988, 994–95 (Fed. Cir. 2009) (concluding that case law for reasonable capability was inapposite where the claim required a particular configuration and recited "protrusions resting upon the closed end of the cover," meaning that the protrusions must be resting upon the cover); *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1369 (Fed. Cir. 2009) ("The claim in *High Tech* requires a structure: a camera 'rotatably coupled' to a body member. In contrast, claim 22 here only requires a capacity to perform a function: 'capable of engaging' magnetic members from the top."). Unless the claim language "only requires the capacity to perform a particular claim element," it is insufficient for the patentee to show that a device is merely capable of infringement. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1329 (Fed. Cir. 2010) (citation omitted).

Here, the Court finds that claims 22-24 recite capability. The language in those claims is analogous to the claim at issue in *ParkerVision*. *Compare ParkerVision.*, 903 F.3d at 1362 (an oscillating signal that "causes said switch module ***to gate*** said bias signal"), *with* '465 patent at 16:11–20, 41–48 (the tray "arranged relative to the receptacle and its opening to prevent hand access into the receptacle," "whereby said front portion of the tray moves towards said lid to continue to impede hand access into the receptacle," and the "tray is movable from a stored position, in dependence upon movement of the lid from its closed to its opened positions, to a block position at said receptacle opening to thereby impede hand access into the receptacle"). The claim terms recite structural features of the sharps container—the tray—with the specific purposes to "impede hand access into the receptacle" and "to prevent hand access into the receptacle," rather than those purposes acting as requirements for how the apparatus actually

operates. Consequently, the reasonably capable standard applies, and Stericycle's PGII containers need only have a tray that is reasonably capable of preventing hand access into the receptacle to infringe.

C. Stericycle's Advertising Materials and FDA § 510(k) Filing

The final preliminary matter for the Court to discuss concerns what evidence it will review as evidence of infringement. Stericycle claims that neither its advertising materials nor its § 510(k) filing to the FDA may be used to prove infringement because these materials are irrelevant and not probative.

First, Plaintiffs request that the Court consider the following statements in Stericycle's advertising materials as evidence of infringement: Stericycle's containers "utilize[] safety/engineering controls that prevent[] access to the contents of the container," "incorporate safety/engineering controls that include limited access to the contents of the container," and result in a "100% sustained reduction in needlesticks." (DRPSF ¶ 16.)

Generally, courts are not prohibited from "using the admissions of a party, whether in the form of marketing materials or otherwise, as evidence in an infringement action; such admissions are entitled to weight along with all other evidence of infringement." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1351 (Fed. Cir. 2007). Nonetheless, documents cannot bring an accused device within a patent's scope when the undisputed facts show that the device fails to meet the claim limitation. *See Regents of Univ. of Minn. v. AGA Med. Corp.,* 717 F.3d 929, 939 (Fed. Cir. 2013) (determining that no reasonable jury could find infringement based on sales materials describing the device as having two disks, where it was clear that the device was not constructed from two physically separate disks or conjoint disks); *MAG Aerospace Indus., Inc. v. B/E Aerospace, Inc.*, 816 F.3d 1374, 1377 (Fed. Cir. 2016) (concluding that testimony and

technical documents providing that the defendant's toilet bowl could be replaced without tools did not create a genuine dispute of fact where the record evidence showed that to release the screw fasteners and remove the bowl, a tool was necessary); *see also Glaukos Corp. v. Ivantis, Inc.*, No. SACV 18-620, 2019 WL 1950297, at *10 (C.D. Cal. Mar. 19, 2019) (finding that video marketing materials could not overcome undisputed evidence about a device's actual specifications, anatomical facts in the prosecution history, and defendant's admissions about the product's relative size); *Whirlpool Corp. v. LG Elecs., Inc.*, 2006 WL 2035215, at *8 (W.D. Mich. July 18, 2006) ("[M]arketing materials cannot override the actual operation of the [device]."). Stericycle cites *Rembrandt Vision Technologies, L.P. v. Johnson & Johnson Vision Care, Inc.*, 725 F.3d 1377, 1379 (Fed. Cir. 2013), for the proposition that advertising materials are irrelevant and inadmissible to prove infringement because such materials are not probative of whether a device really meets the claim limitation. While the Federal Circuit found that generic statements about a device's characteristics could confuse the jury and did not bear on whether the device actually possessed that characteristic within the meaning of the district court's claim construction, it also explained that the district court was within its discretion to exclude that evidence from trial—not that the court was required to do so as a matter of law. *See Rembrandt*, 725 F.3d at 1382–83.

Accordingly, the Court will consider Stericycle's admissions in its advertising materials as evidence of infringement that may create a genuine dispute of fact, except where the undisputed record shows that the PGII container does not actually meet the claim limitation.

Second, Plaintiffs ask the Court to consider Stericycle's statement in its § 510(k) filing that Stericycle's sharps containers employ "a counterbalanced lid design that acts as a protective barrier to keep sharps objects within the container from coming back up through the lid and

anyone from reaching into the container to retrieve sharps waste" (DRPSF ¶ 15) as evidence that Stericycle's products meet the prevent hand access limitation.

The FDA's § 510(k) process allows an applicant to avoid the premarket approval process for a new device if the FDA finds that the device is "substantially equivalent" to an existing device exempt from premarket approval. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (quoting 21 U.S.C. § 360c(f)(1)(A)). Substantial equivalence means that a device has the same intended use as the predicate device, and either has the same technological characteristics as the predicate device or is as safe and effective as the predicate device. 21 U.S.C. § 360c(i)(1)(A). However, numerous courts have found it improper to consider statements regarding substantial equivalence made in § 510(k) filings as evidence of patent infringement. *See, e.g.*, *Abbott Point of Care, Inc. v. Epocal, Inc.*, No. CV-08-S-543-NE, 2012 WL 13162732, at *4–5 (N.D. Ala. Apr. 18, 2012) ("The Federal Circuit has cautioned that evidence supporting a finding of 'substantial equivalence' in the FDA 510(k) context should not be confused with the proof required to support a claim of patent infringement under the Doctrine of Equivalents."); *Ethicon Endo-Surgery, Inc. v. Hologic, Inc.*, 689 F. Supp. 2d 929, 936 (S.D. Ohio 2010) (collecting cases); *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) (collecting cases); *cf. Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1348 n.3 (Fed. Cir. 2008) ("FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries.").

But the cases excluding evidence of statements made in § 510(k) filings are inapposite to the circumstances here. Plaintiffs concede that substantial equivalence for § 510(k) purposes is not dispositive for infringement under the doctrine of equivalents as they involve different inquiries. Instead, Plaintiffs seek to treat Stericycle's statement that its counterbalanced lid design keeps persons from reaching into the container to retrieve sharps waste as an admission that the

PGII container prevents hand access. Contrary to Stericycle's assertion, Plaintiffs are not arguing that Stericycle's statement that the PGII container is substantially equivalent to the commercial embodiment of the '465 patent means that the device is equivalent for patent infringement purposes. As noted above, courts are not restricted from relying on party admissions, whether in marketing materials or in another form, as evidence of infringement. *PharmaStem*, 491 F.3d at 1351. The Court will therefore consider Stericycle's statement in its § 510(k) filing as evidence of infringement that may create a genuine dispute of fact, unless the undisputed evidence shows that the PGII container does not actually meet the claim limitation.

D. Literal Infringement

Turning to Plaintiffs' literal infringement theory, Stericycle asserts that neither the commercialized design nor the testing and sample design of the PGII container literally infringes claims 22-24 because evidence shows that a person can extend a portion of their hand into the containers' receptacle. "To prove literal infringement, the patentee must show that the accused device contains ***each and every*** limitation of the asserted claims." *SIMO Holdings Inc. v. H.K. uCloudlink Network Tech. Ltd.*, 983 F.3d 1367, 1380 (Fed. Cir. 2021) (emphasis in original) (citation omitted). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1340 (Fed. Cir. 2013) (citation omitted). Here, the relevant claim limitation is "prevent hand access into the receptacle."

i. Commercialized Design

For the commercialized design, the Court concludes that no reasonable jury could find that this design is reasonably capable of the prevent hand access limitation pursuant to a literal infringement theory.

First, Stericycle provides several photographs of thirteen adults placing their hands inside of the commercialized design, all of whom could place a portion of their hands near or below the receptacle's fill line. (PRDSF ¶¶ 32–33.) The photographs are accompanied by declarations from Foos and Roshelle Bartholomew, a paralegal for Stericycle's counsel, stating that they directed the individuals to place their hands inside of the container, that they took the photographs, and that the photographs are fair and accurate representations of the persons reaching their hands into the containers. (Def.'s Mem., Ex. 8, Bartholomew Decl. ¶¶ 2–3, Dkt. No. 201-8; Foos Decl. ¶ 11.) And Foos notes that one of the photographs depict him reaching into the container. (Foos Decl. ¶ 11.) Stericycle also offers undisputed testimony from Plaintiffs' counsel and corporate representative, in which they testified that they were able to reach their hand into the container above or to the fill line. (PRDSF ¶¶ 35, 37.)

In opposition, Plaintiffs cite testimony from Daniel Goldstein, Stericycle's former director of strategic sourcing, where he testified that he could not get his fingers past the fill line if he reached his hand into the container. (Def.'s Mem., Ex. 8, Goldstein Dep. Part I 14:9–22, 165:3–11, Dkt. No. 202-8.) They also offer a declaration from Justin Swindells, one of Plaintiffs' counsel, where he states that he attempted to reach his hand into several PGII containers marked as exhibits P50, P52, and P57. (Pls.' Resp. Br., Ex. 2, Swindells Decl. ¶¶ 1–2, Dkt. No. 216-2.) For P50, Swindells reports that he could get his fingers and part of his palm through the opening of the container but could not reach the top of the fill line. (*Id.* ¶ 4.) With respect to P52, he notes that he could get his fingers, but not his palm inside of the opening of the container, and that the tips of his fingers could not reach anywhere near the top of the fill line. (*Id.* ¶ 6.) For P57, Swindells declares that he could barely get the tips of his fingers through the opening, and that it would be impossible for him to get his fingers near the fill line. (*Id.* ¶ 8.) Although Plaintiffs did

not categorize exhibits P50, P52, and P57 as the commercialized design or the testing and sample design, Stericycle provides testimony from Goldstein, indicating that the P50 and P52 containers were manufactured in 2018 and 2019, and the P57 container was manufactured in 2013. (Def.'s Reply Br., Ex. 3, Goldstein Dep. Part III 152:11–24, 156:2–157:14, 167:7–15, 173:13–174:10, 176:17–177:16 , Dkt. No. 225-3.) Without any evidence to the contrary, the Court concludes that the P50 and P52 containers were the commercialized designs, and the P57 container was the testing and sampling design.

In addition, Plaintiffs rely on Stericycle's statements in its § 510(k) filing and promotional materials. In those documents, Stericycle describes its sharps container as designed to keep anyone from reaching into the container to retrieve waste and utilizing safety and engineering features to prevent access to the container's contents. (DRPSF ¶¶ 15–16.) Even so, the Court does not view those statements as creating a genuine issue of material fact because the present record shows that each person was able to extend a portion of their hand into the receptacle beyond the receptacle's opening. Plaintiffs' evidence that persons were not able to reach the fill line of the commercialized design is immaterial. As the Court previously explained, "the receptacle that holds medical sharps and waste thereby substantially eliminating injury or infectious transmission by preventing human contact with medical sharps and waste" refers to the receptacle in which medical waste and sharps are stored where a person's hand, or a portion of their hand can reach such medical waste and sharps stored there. This section can encompass the area above the receptacle's fill line or the entire volume of the receptacle so long as it does not include the section adjacent the opening. In this instance, Plaintiffs have produced no evidence that a person was unable to reach their hand or a portion of their hand beyond the section adjacent the opening of the commercialized design, only that a person was unable to reach the fill line.

Hence, based on the current record, no reasonable jury could conclude that the commercialized design of the PGII container was reasonably capable of containing the prevent hand access limitation of the ’465 patent as required for literal infringement. Summary judgment is thus granted with respect to the literal infringement theory of Plaintiffs’ patent infringement claim for the commercialized design.

ii. Testing and Sample Design

Moving to the testing and sample design, the Court determines that a reasonably jury could find that this design is reasonably capable of the prevent hand access limitation under a literal infringement theory.

Stericycle claims that despite the smaller opening to the container’s interior, a user could still extend part of their hand into the receptacle, although the user may not have been able to reach the fill line. Unlike its argument regarding the commercialized design, Stericycle does not include sample photographs of persons reaching their hands into the receptacle. In support, Stericycle depends on deposition testimony from Foos, where he testified that earlier versions of the PGII container did not infringe because they allowed hand access. (Foos Dep. 127:22–128:13.) It also cites deposition testimony from Mark Dirr, the senior director of engineering at Commercial Plastics, in which he recalled being able to extend his hand beyond the rim of the receptacle of the P57 container, one of the testing and sample designs. (Dirr Dep. 214:4–18.) Stericycle further relies on deposition testimony from Scott Biba, a senior mechanical engineer at Delve, where he described the testing and sample design as having a “passive restraint system” that would have prevented a person from reaching too far into the container to the fill line. (Biba Dep. 10:18–11:3, 140:6–141:12.) Finally, Stericycle references a 2011 letter from counsel at Michael Best & Friedrich LLP, opining that Stericycle’s proposed container allowed hand access

into the receptacle in some positions of the inner and outer doors. (Def.'s Mem., Ex. 16, Michael Best Letter at 5–8, Dkt. No. 202-16.)

Plaintiffs, in contrast, contend that the testing and sample design sometimes does not allow a person to extend their hand into the receptacle such that a part of their fingers extend beyond the fill line. They cite Biba's deposition testimony, where he commented that an eight-year-old female could not reach the fill line of a foam-core model of the 2011 design, and that a five-year-old female would have to be in the circus to reach the container's fill line. (Biba Dep. 112:11–114:5, 123:19–124:1.) Plaintiffs also rely on Swindells's statement that he could barely get the tips of his fingers through the opening of the P57 container, and that it would be impossible for him to get his fingers near the fill line. (Swindells Decl. ¶ 8.) Moreover, Plaintiffs again depend on Stericycle's statements in its advertising materials and § 510(k) filing that its sharps containers preclude persons from reaching into the container to retrieve waste and utilize safety and engineering features to prevent access to the container's contents. (DRPSF ¶¶ 15–16.)

Contrary to Plaintiffs' argument, the receptacle's fill line is not the relevant measure for whether the PGII container prevents hand access into the receptacle. As discussed above, "the receptacle that holds medical sharps and waste thereby substantially eliminating injury or infectious transmission by preventing human contact with medical sharps and waste" refers to the receptacle in which medical waste and sharps are stored where a person's hand, or a portion of their hand, can reach such medical waste and sharps stored there. This section can include the area above the receptacle's fill line or the entire volume of the receptacle so long as it does not include a section adjacent the opening.

The Court finds that there is a genuine issue of material fact regarding whether the testing and sample design prevents a person from extending part of their hand into the receptacle that

holds medical sharps and waste. While Stericycle offers evidence that a person could reach their hand into the receptacle, specifically beyond the receptacle's rim, Plaintiffs introduce conflicting evidence that a person could barely get their fingertips through the container's opening. As the Court noted in its claim construction order, the patent specification does not provide that:

> any part of a person's hand, such as a fingernail or hair, cannot reach or protrude into the receptacle; rather, it details that the hand's reach into the receptacle is restricted to such extent that injury and infectious transmission is substantially eliminated . . . by preventing human contact—which can occur when the hand or a portion of it comes into contact with sharps and other waste stored in the receptacle.

(12/18/18 Mem. Op. and Order at 13–14 (internal quotation marks omitted).) For present purposes, the reach of a person's fingertips can be viewed as analogous to the reach of a person's fingernails if the person's reach into the container is not restricted to such extent that contact cannot occur with sharps and waste stored in the receptacle.

Furthermore, the clarification of the Court's construction of "prevent hand access into the receptacle" indicates that the section of the receptacle holding waste consists of the entire volume of the receptacle, excluding the section adjacent the opening. Drawing reasonable inferences in Plaintiffs' favor, Swindells's statement that he could barely get his fingertips past the container's opening suggest that the testing and sample design prevented him from reaching a portion of his hand into the receptacle, except the opening or section adjacent the opening. Stericycle's admissions in its § 510(k) filing and promotional materials are also appropriate to consider as evidence in Plaintiffs' favor, because the undisputed evidence fails to show that the testing and sample design does not meet the claim limitation.

Viewing the evidence in the light most favorable to Plaintiffs, a reasonable jury could find that the testing and sample design is reasonably capable of satisfying the claim limitation of preventing hand access into the receptacle. Therefore, summary judgment is denied with respect

to the literal infringement theory of Plaintiffs' patent infringement claim for the testing and sample design of the PGII container.

E. Doctrine of Equivalents

As an alternative to their literal infringement theory, Plaintiffs also contends that Stericycle's PGII container infringes claims 22-24 under the doctrine of equivalents. Stericycle, in turn, argues that neither the commercialized design nor the testing and sample design of the PGII container infringe under the doctrine of equivalents because the record shows that a person can extend a portion of their hand into the containers' receptacle—a substantial difference from the claim limitations of the patent-in-suit.

"Under the doctrine of equivalents, 'a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention.'" *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1175 (Fed. Cir. 2020) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997)). In essence, the patentee must show that "the difference between the claimed invention and the accused product or method was insubstantial or that the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1354 (Fed. Cir. 2018) (citation omitted). But an infringement theory under the doctrine of equivalents will fail "if it renders a claim limitation inconsequential or ineffective" (vitiation doctrine). *Edgewell Pers. Care Brands, LLC v. Munchkin, Inc.*, 998 F.3d 917, 923 (Fed. Cir. 2021) (citation omitted). In other words, the vitiation doctrine ensures that the doctrine of equivalents does not nullify a claim element in its entirety. *Id.* Vitiation is a legal conclusion that

equivalence does not exist between the elements. *See UCB, Inc. v. Watson Lab'ys Inc.*, 927 F.3d 1272, 1283 (Fed. Cir. 2019).

In its initial brief for the summary judgment motion, Stericycle argues the following points with respect to the doctrine of equivalents: (1) the differences between the claimed elements of the patent-in-suit and the elements of the PGII container are substantial because evidence shows that persons can extend a portion of their hand into the receptacle; (2) the PGII container does not perform substantially the same function of preventing hand access into the receptacle or achieve substantially the same result of making it so that a person cannot extend a portion of their hand into the receptacle, because the record shows that persons can extend a portion of their hand into the receptacle through the opening between the lid and tray; and (3) applying the doctrine of equivalents here would vitiate the claim limitations. Meanwhile, in their response brief, Plaintiffs contend that Stericycle "has not pointed to any specific way in which it does not perform that same function in substantially the same way with substantially the same result, and this factual issue remains for trial." (Pls.' Resp. Br. at 14, Dkt. No. 216.) In its reply brief, Stericycle underscores that Plaintiffs failed to respond to its argument or explain how the PGII containers perform substantially the same function, way, and result as the patent-in-suit; consequently, Stericycle claims that Plaintiffs' response mandates entry of summary judgment in it favor.

The Court agrees. "A patentee must provide particularized testimony and linking argument as to the insubstantiality of the differences between the claimed invention and the accused device or process, or with respect to the function, way, result test when such evidence is presented to support a finding of infringement under the doctrine of equivalents." *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed. Cir. 2015) (citations omitted).

This requirement is applicable in the summary judgment context as well. *AquaTex Indus., Inc. v. Techniche Sols.*, 479 F.3d 1320, 1328 (Fed. Cir. 2007). "Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process" is inadequate. *Gemalto S.A. v. HTC Corp*., 754 F.3d 1364, 1374 (Fed. Cir. 2014) (citation omitted). The Federal Circuit has explained what forms of evidence are necessary to provide such particularized testimony:

> [W]hen the patent holder relies on the doctrine of equivalents, as opposed to literal infringement, the difficulties and complexities of the doctrine require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents.

Id. at 1329.

Here, Plaintiffs failed to provide particularized testimony from a person skilled in the art that addressed equivalents on a limitation-by-limitation by basis, that described how the differences between the patent-in-suit and the PGII containers are insubstantial, or that examined the function, way, result test. Accordingly, summary judgment is granted with respect to the doctrine of equivalents theory of Plaintiffs' patent infringement claim for both the commercialized design and testing and sample design of the PGII container.

IV. Liability for Manufactured Designs Shipped to Foreign Countries

Stericycle next seeks summary judgment as to its liability for infringement for any manufactured design of the PGII container shipped to foreign countries. Specifically, it argues that the patent infringement statute requires relevant action to occur within the United States, yet for the designs of the PGII container manufactured by a third party and shipped to foreign countries, Stericycle committed no allegedly infringing acts within the United States.

"[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). "[A] strong policy against extraterritorial liability exists in the patent law." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 831 F.3d 1369, 1377 (Fed. Cir. 2016) (citation omitted). Section 271(a) imposes liability only for "infringing activities that occur within the United States." *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1375 (Fed. Cir. 2005). Nonetheless, a defendant may still be liable for patent infringement even if it uses a third party to manufacture the accused device on its behalf in the United States. *See Crowell v. Baker Oil Tools*, 143 F.2d 1003, 1004 (9th Cir. 1944); *see also Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1118 (Fed. Cir. 2004) (noting that *Crowell* "held that one cannot escape liability for infringement as a manufacturer of infringing products simply by employing an agent or independent contractor to carry out the actual physical manufacturing"); *cf. Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013) (holding that a party must commit all the necessary infringing activities, either personally or vicariously, to be liable for direct patent infringement under section 271(a)).

Here, it is undisputed that Commercial Plastics and Xten Industries manufactured and shipped all designs of Stericycle's PGII container, some of which were shipped to the United Kingdom and Canada. (PRDSF ¶¶ 20, 23, 29.) Nevertheless, summary judgment is inappropriate because, as noted above, Stericycle may still be liable for infringement for products manufactured by Commercial Plastics and shipped to foreign countries, even though Stericycle employed Commercial Plastics to manufacture products for it. In addition, there is no evidence that

Commercial Plastics or Xten Industries manufactured the PGII container outside of the United States. Summary judgment on this ground is thus denied.

V. Marking: Limitation of Damages

Finally, Stericycle asserts that Plaintiffs are not entitled to damages for any alleged infringement occurring prior to the date they filed suit on November 30, 2015, because they failed to produce proof that they substantially and continuously marked their patented products before then.

"Pursuant to 35 U.S.C. § 287(a), a patentee who makes or sells a patented article must mark his articles or notify infringers of his patent in order to recover damages." *Lubby Holdings LLC v. Chung*, 11 F.4th 1355, 1359 (Fed. Cir. 2021) (citation omitted). A patentee can provide notice by either of two ways: (1) marking the article with the patent number ("constructive notice") or (2) notifying the alleged infringer of the patent and the alleged infringement ("actual notice"). *See Gart v. Logitech, Inc.*, 254 F.3d 1334, 1345 (Fed. Cir. 2001). If a patentee fails to provide notice of his right by marking his articles, he is barred from recovering damages before the date of actual notice. *Id.* While the patentee bears the burden of showing compliance with the marking statute, an alleged infringer challenging the patentee's compliance with the statute has an initial burden of production to identify the patented articles it believes are unmarked. *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1367–68 (Fed. Cir. 2017). Plaintiffs do not challenge that Stericycle satisfied its initial burden of production.

A. Actual Notice

Stericycle first asserts that Plaintiffs failed to provide Stericycle with notice of any alleged infringement prior to the present suit. To constitute actual notice, "notice must be of the infringement, not merely notice of the patent's existence or ownership." *Lubby*, 11 F.4th at 1360

(internal quotation marks and citation omitted). Specifically, actual notice "requires the affirmative communication of a specific charge of infringement by a specific accused product or device." *U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1375 (Fed. Cir. 2007) (citation omitted).

Here, Plaintiffs argue that Stericycle had actual notice of its infringement as of 2011, when Stericycle received a document declaring that the Sharpsmart container was protected by the '465 patent. Stericycle does not dispute that it received the referenced document. The stated purpose of that document, titled "Confidential Information Memorandum," was to provide parties who were interested in pursuing a transaction with Daniels Corporation Group Holdings Pty Ltd with an in-depth investigation of the company. (Def.'s Reply Br., Ex. 4, Lazard Mem. at 3, Dkt. No. 225-4.) In the IP portfolio section, the memorandum reports that the "Daniel Sharpsmart system is an FDA-approved medical device system with meaningful patent protection," including U.S. Patent No. 6,250,465, a patent for a sharps container. (*Id.* at 5.)

Although the memorandum establishes that Stericycle had notice of the '465 patent's existence, the memorandum does not accuse Stericycle of infringement nor does it identify any of Stericycle's allegedly infringing products—as required for establishing actual notice. Since the memorandum is the sole evidence offered by Plaintiffs to support their actual notice claim, no reasonable jury could find that Stericycle had actual notice of its alleged infringement.

B. Constructive Notice

Turning to constructive notice, Stericycle argues that Plaintiffs have not produced proof that they marked the Sharpsmart container with the '465 patent substantially and continuously before they filed suit in 2015. To satisfy constructive notice, Plaintiffs must show that they marked substantially all the Sharpsmart containers during the relevant period, and the marking

was "substantially consistent and continuous." *Nike, Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1446 (Fed. Cir. 1998).

The Court first surveys the evidence on this point. Plaintiffs answer in an interrogatory response that they complied with the notice requirements of 35 U.S.C. § 287, and that Sharpsmart marks its various sharps containers with the appropriate patents. (Def.'s Mem., Ex. 35, Pls. Resp. to Third Set of Interrogs. at 4, Dkt. No. 201-35.) Plaintiffs also submit two documents, which it alleges are maintained in the ordinary course of business, that depict a collection of labels for Sharpsmart's reusable sharps containment system with U.S. Patent No. 6,250,465. (*See* Pls.' Resp. Br., Ex. A, Sharpsmart Labels April 2022, Dkt. No. 216-4; Pls.' Resp. Br., Ex. B, Sharpsmart Historical Labels, Dkt. No. 216-5.) The document with the first collection of labels further contains a notation in the document's heading, stating that the labels are the "[c]urrent labels as of April 2022." (Sharpsmart Labels April 2022 at 2.) The second document similarly has notations beside each label, listing the specific release date of that label. (Sharpsmart Historical Labels at 2–7.) The release dates range from 2006 to 2019. (*Id.*)

Stericycle challenges both sets of labels as insufficient to substantiate Plaintiffs' alleged marking. For the first document with the labels and notation "current labels as of April 2022," Stericycle contends that this document is immaterial because the relevant issue before the Court is marking before November 2015. The Court concurs, so it will not consider this document as evidence of Plaintiffs' compliance with the marking statute prior to suit.

For the second document with the labels and accompanying notation of the labels' release date, Stericycle claims that the notations are inadmissible hearsay, and that Plaintiffs put forth no evidence that the document satisfies the hearsay exception for business records. The Court agrees that the notations are hearsay—as Plaintiffs are offering them to prove the truth of when the label

was released and used. *See* Fed. R. Evid. 801(c). In addition, Plaintiffs have not introduced any proof that the document could be admissible as a business record. At the summary judgment stage, a party seeking admission of a document as a business record must establish that the "document has sufficient indicia of trustworthiness to be considered reliable," generally by submitting an affidavit of a person who would be authorized to introduce the record as evidence at trial. *Thanongsinh v. Bd. of Educ*., 462 F.3d 762, 777 (7th Cir. 2006) (internal quotation marks and citation omitted). This requirement does not apply when the opposing party has previously relied on that same document for its accuracy or has otherwise conceded the accuracy of the document. *Id*. at 778. Here, Plaintiffs have provided no such affidavit. As a result, the Court will not consider the notations for purposes of summary judgment. However, it will consider the set of labels in the second document—excluding the accompanying notations—as evidence because the document would no longer contain a "statement" as defined by the rule against hearsay. *See* Fed. R. Evid. 801(a) ("Statement means a person's oral assertion, written assertion, or nonverbal conduct, if the person intended it as an assertion.").

Next, Stericycle claims that Plaintiffs' conclusory statements that they complied with the marking statute and marked the Sharpsmart containers are insufficient to preclude summary judgment. Stericycle relies on *Von Holdt v. A-1 Tool Corp.*, 714 F. Supp. 2d 863 (N.D. Ill. 2010), for the proposition that a patentee's statement in an interrogatory response or deposition testimony that it complied with marking requirements, without any other evidence of compliance, is insufficient to avoid summary judgment. It is true that the court in *Von Holdt* concluded that "evidence of current company policy and practice, without any other evidence of compliance with the marking requirement during the relevant time period, is insufficient to overcome a motion for summary judgment." 714 F. Supp. 2d at 871. That said, Stericycle ignores Federal Circuit and

other case law suggesting that an affidavit or statement that the patentee complied with marking requirements can be sufficient evidence to create a disputed issue of fact at the summary judgment stage. *See, e.g.*, *Sentry Prot. Prods., Inc. v. Eagle Mfg. Co.*, 400 F.3d 910, 918 (Fed. Cir. 2005) (determining that the district court erred in granting summary judgment in favor of the defendant when the patentee offered an affidavit stating that its products were marked along with sales documents during the alleged period of infringement); *cf. SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1378 (Fed. Cir. 2010) (finding sufficient evidence to support the jury's determination that the patentee complied with the marking statute where the patentee introduced evidence that one of its products—albeit with an unknown manufacturing date —had a label listing the patent, and an executive testified that the products were always marked and the company had a policy of marking its products); *Cordance Corp. v. Amazon.com*, *Inc.*, 631 F. Supp. 2d 484, 500 (D. Del. 2009) (noting that a patentee's interrogatory answer, stating that the products were marked with the relevant patent numbers, "may very well have let it avoid summary judgment" if the defendant had moved for summary judgment on the marking issue); *Sandbagger Corp. v. City of Youngsville*, No. CIV A 6:08-1188, 2009 WL 2628859, at *3 (W.D. La. Aug. 25, 2009) (concluding that a genuine dispute of fact existed where a company's president stated in an affidavit that the products were marked with the patent number and defendants offered no evidence to the contrary).

At bottom, the Court determines that Plaintiffs' interrogatory response combined with the document depicting the labels for the Sharpsmart container are sufficient to create a genuine dispute of fact concerning Plaintiffs' compliance with the marking statute —particularly when drawing the reasonable inference in Plaintiffs' favor that they applied the labels to the containers. Summary judgment is thereby denied.

CONCLUSION

For the foregoing reasons, Stericycle's renewed motion for summary judgment of noninfringement (Dkt. No. 201) is granted in part and denied in part. Summary judgment is granted with respect to Plaintiffs' patent infringement claim under both a literal infringement theory and doctrine of equivalents theory for the commercialized design of Stericycle's PGII container. Summary judgment is also granted for the testing and sample design pursuant to a doctrine of equivalents theory, but denied under a literal infringement theory. Further, summary judgment is denied with respect to manufactured designs of the PGII container shipped to foreign countries and damages for any infringement prior to the filing date of the present suit due to Plaintiffs' alleged failure to mark the Sharpsmart container with the '465 patent.

ENTERED:

Dated: September 28, 2025

Andrea R. Wood
United States District Judge